

# Using the ‘Rule of Five’ to Determine Ecologically Protective Clean-Up Goals at Superfund Sites

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# Objectives

- To provide a simple & logical method for the development of defensible clean up goals following the ecological risk characterization.
  
- To provide a flexible framework within the risk range from which the clean up number can be selected.



# Risk Management Considerations

- The method proposed here brings the lines of evidence from the ERA (i.e., science) into the decision process for establishment of clean up goals
  - Tool to enable meeting the requirements of a risk assessment
- The approach gives decision makers a visualization tool for working within the risk range to derive a technically defensible, ecological risk-based remediation goal.



# Introduction

- Weight of evidence evaluation has been used in Superfund site risk assessments
  - Often determines degree of risk (i.e., high, medium or low risk) in risk characterization
  - Unclear with regards to developing clean up numbers (risk management)
- It is not appropriate after a rigorous ecological risk assessment to base the decision on one end or the other of the NOAEL-to-LOAEL risk range—*The clean up should occur within this range*



# Introduction

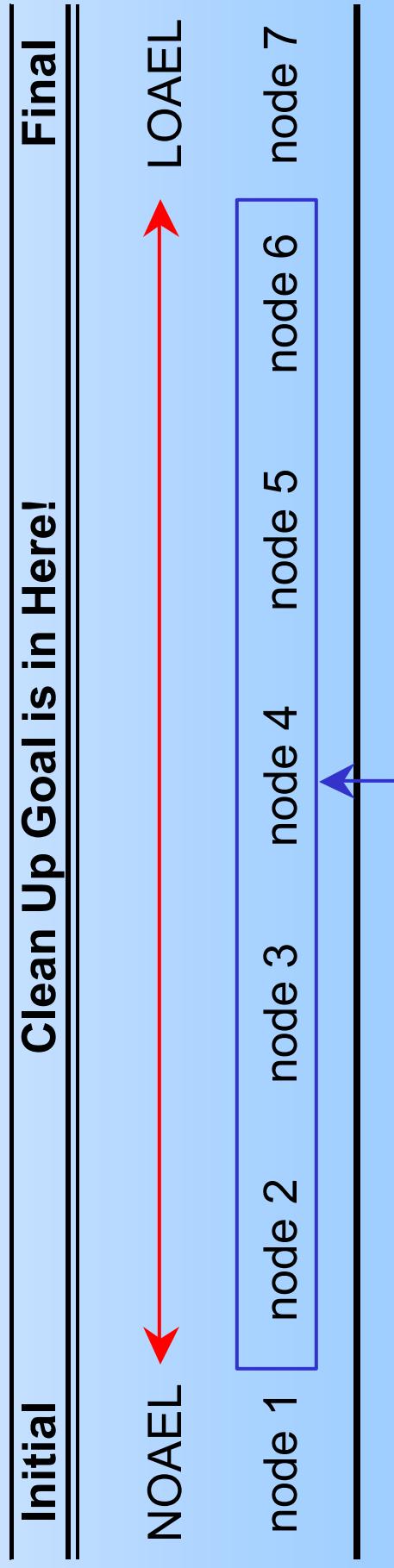
- There are typically no more than three lines of evidence for a given assessment endpoint. Therefore, we provide five positions within the risk range from which a clean up goal can be selected
  
- The “Rule of Five” is especially useful for selecting a protective value within a wide risk range



# Technical Approach

- A clean up goal can be selected within the NOAEL-LOAEL risk range of an assessment endpoint based on consideration of points in a geometric progression:

$$A_n = A_0 * r^{n-1} \quad (\text{eq. 1})$$



The five nodes between the NOAEL and LOAEL are considered



# Technical Approach

To calculate the constant,  $r$ , the equation is:

$$r = e^{\left[ \frac{\ln(A_n) - \ln(A_0)}{n-1} \right]} \quad (eq. 2)$$

Node 2 = NOAEL \*  $r^{2-1}$

⋮

LOAEL = NOAEL \*  $r^{7-1}$



# Justification

- Mathematics and statistics support preference of a geometric over an arithmetic progression for this purpose (environmental data are more likely a log-normal distribution)
- EPA has used geometric mathematics in developing protective water quality criteria
  - SMAV, FACR (final Acute-to-Chronic Ratio), WERs
- Used in the NCP as a method of choosing parameter values for assigning groundwater mobility parameters (e.g., geomeans of water solubility and  $K_d$  data)
- Used in development of EcoSSLs

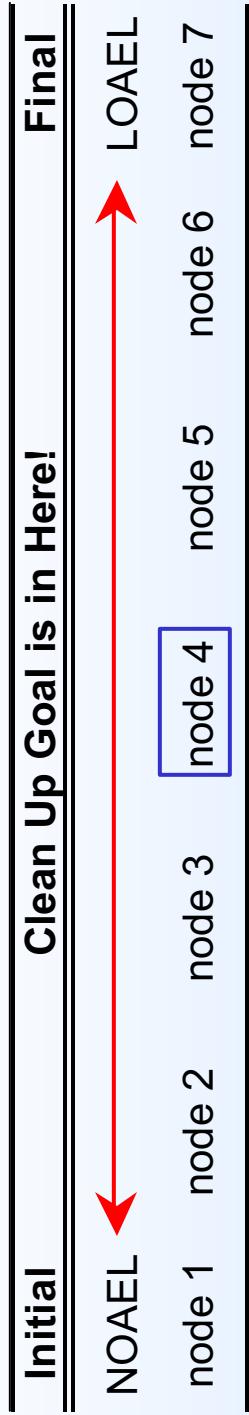


# Selecting the Value

- *The ERA studies and analyses have already been conducted by the time we use the Rule of Five*
- We need to make a decision on the value from within the NOAEL-to-LOAEL range that will be protective of ecological receptors.
  - This ecological risk information is then considered with other site factors to make the risk management decision



# Application

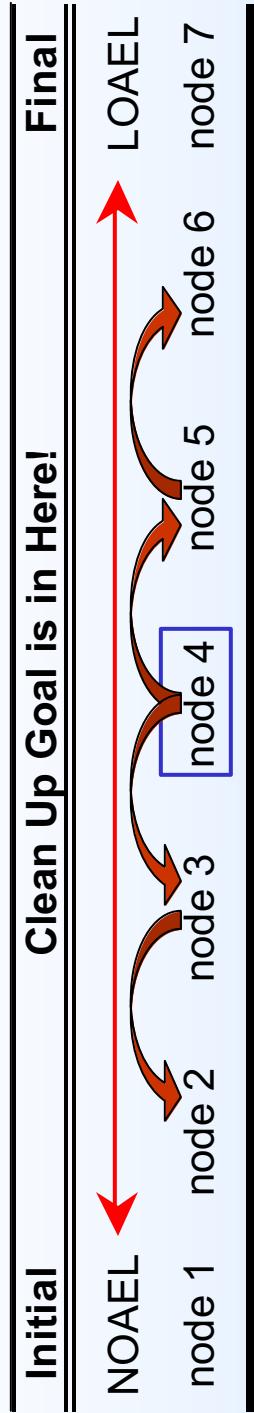


➤ **Starting Assumption:** The third point above the low end of the risk range is protective of growth and reproduction endpoints.

- This point is equivalent to the geometric mean of the NOAEL and LOAEL.
- If the basis of the risk range is survival or mortality the initial point is the second point above the NOAEL.



# Application

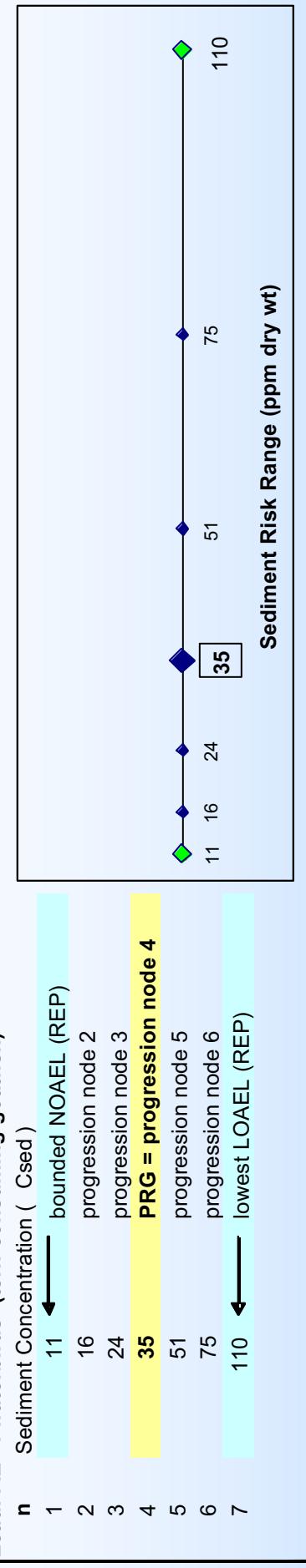


- **Discriminant lines of evidence** provide information that can be used to raise or lower the clean up value from the initial starting point
- **Equivocal lines of evidence** include tests or measures that do not technically support moving about the nodes
  - Results are either confounded, unable to discriminate among experimental points, or highly uncertain

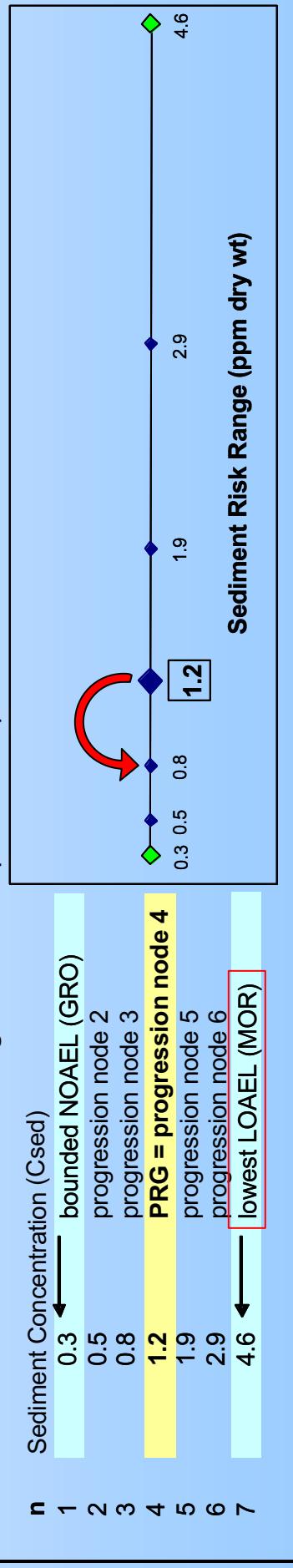


# Pearl Harbor Sediments ERA

Lead: AE -4 waterbirds (tern consuming goatfish)



Total PCB NOAA18: AE-1 invertebrates living in sediments (macrofauna)





# Application

## 4,4'-DDE

		1	2	3	4	5	6	7
AE#3	Benthic Community	0.002	0.004	0.008	0.013	0.024	0.042	0.075
AE#4	Piscivorus Bird	0.02	0.031	0.045	0.068	0.1	0.15	0.2

## 4,4'-DDT

		1	2	3	4	5	6	7
AE#3	Benthic Community	0.001	0.003	0.011	0.037	0.12	0.41	1.4
AE#4	Piscivorus Bird	0.44	0.65	0.95	1.4	2	3	4.4

## Total DDX

		1	2	3	4	5	6	7
AE#3	Benthic Community	0.12	0.19	0.3	0.46	0.72	1.1	1.7
AE#4	Piscivorus Bird	0.12	0.18	0.26	0.38	0.56	0.83	1.2



# Discussion

- The Rule of Five has it's greatest value in determining a clean up goal in those risk ranges where there is an order of magnitude or more between the NOAEL and LOAEL
- However, it creates a useful model for supporting a specific risk based number in situations where there is a relatively small risk range.
- The approach also allows some of the ecological parameters that do not lend themselves to numeric weighting (e.g., species diversity, numerical abundance, functional attributes) to be incorporated into the risk assessment where they have been excluded previously as non-decisional.

# Discussion

- In numerous ERAs, scientific studies were weighted on a subjective basis
  - How the lines of evidence were combined was inconsistent
  - A particular outcome can be favored depending on who conducts the analysis.
  - Transparency was lost and the outcome tended to be High, Medium or Low risk.
- These distinctions were not particularly useful for the remedial managers as one was never sure if high risk required remediation or if low risk really meant acceptable risk.





# Conclusion

- The Rule of Five is useful in ensuring compliance with the EPA policy requirement that a risk assessment determines numerical clean-up goals
- The selected goal within the risk range:
  - More transparent and easily explained to the public
  - The clean-up goal is a point that the risk managers can understand and incorporate into remedial decisions